April 3rd, 2003

ATTN: Docket No. 02N-0278

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Docket No. 02N-0278
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir/Madam:

Refreshments Canada is pleased to submit comments in response to the proposal of the U.S. Food and Drug Administration's (US-FDA) regarding the prior notice of imported food (68 Fed. Reg. 5428, February 3rd, 2003).

As noted in the preamble to this rulemaking, the events of September 11th, 2001 highlighted the need to enhance the security of the North American food supply. The refreshment beverages industry supports the overarching goals of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the US-FDA's efforts to implement Title III of the Act. Refreshments Canada and its member companies recognize the unique nature of this rulemaking and feel a shared sense of responsibility with the US-FDA to ensure the security of the North American food supply. It is therefore our intent to offer constructive ideas that will enhance food security while creating a system that is both workable and efficient.

Introducing Refreshments Canada

Refreshments Canada is the premier trade association representing the broad spectrum of brands and companies that manufacture and distribute the majority of non-alcoholic liquid refreshment beverages consumed in Canada. Refreshments Canada member companies produce more than 30 brands of juices, juice drinks, bottled waters, sports drinks, ready-to-serve iced teas and coffees, new-alternative beverages, carbonated soft drinks, energy drinks and other non-alcoholic beverages. In addition, the vast majority of the beverage licensors who manufacture concentrates and/or syrups – from which soft drinks and other beverages are made – are members of Refreshments Canada. It is on behalf of these members that we submit these comments.

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Summary of the Refreshments Canada position

Refreshments Canada suggests that three changes be made to FDA's proposal:

1. that the prior notice requirements for imported foods contain an exemption for food samples destined solely for analytical use
2. that the prior notice system contain a "blanket prior notice provision" that would allow firms – that in their ordinary and regular course of business ship product into the United States – to file a prior notice that would cover shipments for up to one year
3. that the scope of the information required for inclusion in the prior notice be narrowed [e.g. eliminate proposed requirement for lot numbers and/or product codes; apply the prior notice submission to an entire shipment rather than to each food item]

Detailed comments

Major beverage companies operating in Canada typically also have facilities located in the United States, as well as throughout the rest of the world. Beverages, as well as concentrates, ingredients and packaging materials are routinely involved in international commerce.

A considerable amount of commerce routinely involves shipments between Canada and the United States (and sometimes Mexico).

In addition, it is important to recognize that many facilities operate 24 hours a day, 7 days a week. Shipments – whether they contain raw materials or packaging – often cross international boundaries within a matter of only a few hours after they are produced and loaded onto a trailer. These shipments occur 24 hours a day, 7 days a week.

Analytical Samples:

The extensive quality assurance programs associated with the beverage industry are well known throughout the food industry and around the world. These programs involve four primary types of analytical sampling:

1. routine quality assurance samples;
2. non-routine or investigative quality assurance samples;
3. samples of ingredients or packaging from potential suppliers; and
4. consumer-initiated samples.

None of these samples enter the US food supply; rather; they are used for analytical purposes only.

Typically, these samples are small in size. They are also shipped directly to a laboratory or other non-retail facility such as a corporate testing lab and are clearly labelled as being "samples" or "for analytical purposes only".

Routine quality assurance samples are frequently shipped by production facilities and from the marketplace to corporate laboratories. One major company – headquartered in the US – alone receives over 10,000 such samples from outside the US each year. These include a significant number coming from Canada. That American corporate laboratory receives no prior notice that these samples are being shipped.

Likewise, suppliers routinely submit samples of ingredient and/or packaging materials to our companies' laboratories. These samples are small, often weighing less than 115 g (4 oz.). The samples are analyzed for purposes of evaluating potential new suppliers and assuring the quality of ingredients and packaging materials from existing suppliers. Again, one American beverage company alone reviews over 20,000 samples from suppliers outside the US each year. Again, a significant number of these samples come from Canada. Again, the American corporate laboratory receives no prior notice of the shipments of these analytical samples.

Consumer-initiated samples from outside the US pose an even more problematic scenario. From time to time, a consumer will report a situation that prompts a desire to perform testing on a sample in order to rule out concerns about a larger lot of product being sold at the retail level. Time is of the essence in completing analytical testing on these samples to determine whether an issue exists. These samples are therefore shipped to a corporate laboratory where they are then given the highest priority. Delays in this process would be costly and could represent a potential threat to public health.

The same applies to other non-routine or investigative samples. If a manufacturer suspects that a finished product does not meet the intended specifications, priority testing is needed to determine the next steps to be taken relative to a timely resolution of the situation. Again, these samples are not intended for human consumption and are disposed of at the corporate laboratory.

Recognizing that the intent of both the Bioterrorism Act and US-FDA's prior notice of imported food proposal is to address the security of foods and ingredients entering the US food supply, it is only reasonable to exempt routine quality assurance samples that are not intended for consumption and will not enter the US food supply. The large number of these samples will otherwise

needlessly overburden FDA's prior notice system and will serve no useful purpose.

Refreshments Canada proposes that if the sample shipments are

- addressed to and received by only permanently established analytical facilities,
- used solely for analytical purposes and are properly disposed of in a manner that precludes human consumption, and are
- generally small in size and volume,

then an exemption from "prior notice" [as currently proposed] is warranted.

Refreshments Canada also suggests that in addition to these conditions, the analytical facility be allowed to file a "blanket" notice to cover these shipments [as discussed below].

Blanket Prior Notice Provision

As previously noted, a considerable amount of international commerce occurs in the beverage industry. International shipments – especially between Canada and the US – routinely occur 24 hours a day, seven days a week. Many of these shipments occur within hours of the product being manufactured and loaded onto a trailer. Most of these shipments are predictably consistent as to their general content.

A mechanism is needed to minimize the impact of commerce by allowing a firm to file a "blanket" prior notice that would cover an extended period of time-for example, one year. Firms would be allowed to amend their Prior Notice Submission when the salient details of the shipment become known. For example, a firm may import bottled water from Canada for sale in the United States. The only variable may be the quantity per shipment, the size of the individual packages contained within the shipment, and the number of shipments per day or week.

The "blanket" Prior Notice Submission would still provide FDA with the required information to afford the Agency adequate time to adjust its inspection efforts, if warranted. For example, a "blanket" submission would have identified the country of origin, the shipper, the manufacturer and the anticipated port of entry. An Amendment would then be filed to furnish any other required data.

Scope of Information

The scope of the information that the US-FDA proposes to be included in a prior notice submission needs to be narrowed. Some of this information goes beyond both the requirements and the intent of the Bioterrorism Act and is unduly burdensome. This is especially true when combined with the minimum "noon of the day before" timeframe proposed by the US-FDA.

As previously noted, international shipments – especially between Canada and the US – routinely occur 24 hours a day, seven days a week. Many shipments currently cross international borders within hours of the product being manufactured.

First, the prior notice submission should apply to the entire shipment of food, rather than to each individual food item. Under the proposal, a separate prior notice would be required for each flavour of beverage and for each package size. This is wasteful and inefficient.

Under the proposed rule, each food item would require a separate prior notice. This is a significant burden for the beverage industry. Typically, shipments of soft drinks and other beverages will involve a number of flavours, as well as a variety of package sizes. A shipment of soft drinks for example, may contain colas, diet colas, lemon-lime products, root beers, etc. In addition, the multiple package types and sizes within those flavour groups could result in dozens (if not hundreds of food items) all on one trailer. Such detailed information would not provide the US-FDA with any meaningful information, nor would such information even be available at the time that the US-FDA is requesting it.

Further, information such as lot numbers and production codes would create even more categories of food items under the US-FDA's proposed rule. In addition, these numbers and codes are often not even known until the product is actually loaded on trucks for transport, which often occurs within hours of the shipment reaching the border.

Adherence to requirements under the current proposal will result in a logjam of useless information overloading the prior notice submission system. Refreshments Canada strongly suggests that the US-FDA narrow the scope of information that it is seeking in its prior notice submission to general product categories (for example, soft drinks) and eliminate entirely the request for lot numbers and product codes.

Conclusion

Refreshments Canada recognizes the challenges that face the US-FDA in implementing Section 307 of the Bioterrorism Act. The system proposed by the US-FDA integrates some elements of existing US Customs regulations.

However, the proposal also places additional requirements on the food industry. It is likely that the US-FDA has underestimated the impact that these requirements – if implemented as proposed – will have on international commerce.

The inclusion of quality assurance samples – intended for analytical use only – in prior notice submission will needlessly overburden the entire system. These samples should be exempt from prior notice submission requirements, or alternatively the US-FDA should allow a "blanket" notice to cover them.

The US-FDA A should also consider a "blanket" prior notice provision. Routine shipments – especially those from Canada– will otherwise be disproportionately affected.

Likewise, the scope of information required by the US-FDA in its proposal should be narrowed in the final rule. Lot numbers and product codes are often unknown in the period that the US-FDA has proposed.

The three changes that Refreshments Canada recommends be made to the US-FDA's proposal will:

- result in a more efficient and workable system, and
- eliminate unnecessary reporting which will otherwise clog the system.

These changes will also result in greater enhancement of the food security system.

Respectfully submitted on behalf of the members of Refreshments Canada

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